

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing (day/month/year) 15 NOV 2004	
Applicant's or agent's file reference 1700-002	REPLY DUE within 1 months/days from the above date of mailing
International application No. PCT/US03/22011	International filing date (day/month/year) 10 July 2003 (10.07.2003)
Priority date (day/month/year) 13 July 2002 (13.07.2002)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 39/38, and US Cl.: 424/184.1, 192.1, 234.1, 264.1	
Applicant THE UNIVERSITY OF GEORGIA RESEARCH FOUNDATION, INC.	

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☒ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 13 November 2004 (13.11.2004).

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Robert A. Zeman <i>F. Roberts</i> Telephone No. (571) 272-1600
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WRITTEN OPINION

International Application No.

PCT/US03/22011

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-22, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the claims:
 pages 23-29, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the drawings:
 pages 1-10, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the sequence listing part of the description:
 pages 1-3, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.

PCT/US03/22011

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

- ☒ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-4, 25-29 and 50-62.

WRITTEN OPINIONInternational application No.
PCT/US03/22011**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>3-4, 27-28, 51-52 and 55-62</u>	YES
	Claims <u>1-2, 25-26, 29, 50 and 53-54</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-4, 25-29 and 50-62</u>	NO
Industrial Applicability (IA)	Claims <u>1-4, 25-29 and 50-62</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 2. Citations and Explanations:

Claims 1-2, 25-26, 29, 50 and 53-54 lack novelty under PCT Article 33(2) as being anticipated by Kodama et al. (U.S. Patent 5,766,594). Kodama et al. disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507.

Claims 1-2, 25-26, 29, 50 and 53-54 lack novelty under PCT Article 33(2) as being anticipated by Kodama et al. (U.S. Patent 5,621,076). Kodama et al. disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507.

Claims 1-2, 25-26, 29, 50 and 53-54 lack novelty under PCT Article 33(2) as being anticipated by Saito et al. (U.S. Patent 5,489,430). Saito et al. disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507.

Claims 1-2, 25-26, 29, 50, and 53-54 lack novelty under PCT Article 33(2) as being anticipated by Radland et al. (U.S. Patent 5,004,607). Radland et al. disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507.

Claims 1-2, 25-26, 29, 50 and 53-54 lack novelty under PCT Article 33(2) as being anticipated by Nippon Zeon Co., LTD (EP 0 603 406 A1). Nippon Zeon Co., LTD disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507.

Claims 1-4, 25-29 and 50-62 lack an inventive step under PCT Article 33(3) as being obvious over Kodama et al. (U.S. Patent 5,766,594). Kodama et al. disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507. The aforementioned reference does not explicitly disclose the

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

parameters recited in claims 3-4, 7-8, 11-12, 15-16, 19-20, 23-24, 27-28, 31-32, 35-36, 39-40, 43-44, 47-48, 51-52 and 55-62. However, said parameters are deemed to be obvious variations of the disclosed methods.

Claims 1-4, 25-29 and 50-62 lack an inventive step under PCT Article 33(3) as being obvious over Kodama et al. (U.S. Patent 5,621,076). Kodama et al. disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507. The aforementioned reference does not explicitly disclose the parameters recited in claims 3-4, 7-8, 11-12, 15-16, 19-20, 23-24, 27-28, 31-32, 35-36, 39-40, 43-44, 47-48, 51-52 and 55-62. However, said parameters are deemed to be obvious variations of the disclosed methods.

Claims 1-4, 25-29 and 50-62 lack an inventive step under PCT Article 33(3) as being obvious over Saito et al. (U.S. Patent 5,489,430). Saito et al. disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507. The aforementioned reference does not explicitly disclose the parameters recited in claims 3-4, 7-8, 11-12, 15-16, 19-20, 23-24, 27-28, 31-32, 35-36, 39-40, 43-44, 47-48, 51-52 and 55-62. However, said parameters are deemed to be obvious variations of the disclosed methods.

Claims 1-4, 25-29 and 50-62 lack an inventive step under PCT Article 33(3) as being obvious over Ragland et al. (U.S. Patent 5,004,607). Ragland et al. disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507. The aforementioned reference does not explicitly disclose the parameters recited in claims 3-4, 7-8, 11-12, 15-16, 19-20, 23-24, 27-28, 31-32, 35-36, 39-40, 43-44, 47-48, 51-52 and 55-62. However, said parameters are deemed to be obvious variations of the disclosed methods.

Claims 1-4, 25-29 and 50-62 lack an inventive step under PCT Article 33(3) as being obvious over Nippon Zeon Co., LTD (EP 0 603 406 A1). Nippon Zeon Co., LTD disclose methods of immunizing birds of the order Galliformes by the administration of formulations comprising *Mycoplasma gallisepticum* wherein said *Mycoplasma gallisepticum* has similar identifying characteristics to *Mycoplasma gallisepticum* deposited with the ATCC with the designation PTA-4507. The aforementioned reference does not explicitly disclose the parameters recited in claims 3-4, 7-8, 11-12, 15-16, 19-20, 23-24, 27-28, 31-32, 35-36, 39-40, 43-44, 47-48, 51-52 and 55-62. However, said parameters are deemed to be obvious variations of the disclosed methods.

Claims 1-4, 25-29 and 50-62 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.